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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/905,289	07/13/2001	David Ian Rosnick	5051.518	3878
20792	7590	12/15/2003	EXAMINER	
MYERS BIGEL SIBLEY & SAJOVEC			ALLEN, MARIANNE P	
PO BOX 37428			ART UNIT	
RALEIGH, NC 27627			PAPER NUMBER	
			1631	
DATE MAILED: 12/15/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 09/905,289	Applicant(s) ROSNICK ET AL.	
	Examiner Marianne P. Allen	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-37 is/are pending in the application.
- 4a) Of the above claim(s) 23-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-2 and 4-37 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Applicant's arguments filed 9/4/03 have been fully considered but they are not persuasive.

Claim 3 has been cancelled. Claims 1-2 and 4-22 are under consideration by the examiner.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant is advised that should claim 8 be found allowable, claim 9 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). In view of the amendments to these claims, claims 8 and 9 now appear to be identical claims. Clarification is requested.

Election/Restrictions

This application contains claims 23-37 drawn to an invention nonelected without traverse in Paper No. 8.

Claim Rejections - 35 USC § 112

Claims 5 and 14-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

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Claims 5 and 14-20 have been amended. No basis has been pointed to in the specification to support these changes and none is apparent.

Claims 1-2 and 4-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is an enablement rejection.

This rejection is maintained for reasons of record.

Applicant's arguments are not persuasive and fail to address how one of skill in the art is supposed to analyze binding strengths to determine whether a pattern is sufficiently periodic to indicate efficient translation.

While determining binding strength may be routine in the art, applicant's claimed invention is directed to screening for efficient translation and the connection between these two concepts is what is lacking.

For example, if binding strengths for a nine nucleotide sequence are 1-2-3-1-2-3-1-2-3 is this the appropriate periodicity and phase to correlate to efficient translation? What about 1-4-9-1-4-9-1-4-9 or 1-1-1-2-2-2-3-3-3 or 3-1-2-3-1-2-3-1-2 or 3-1-2-1-1-1-1-2-3? The specification does not teach how to interpret patterns to make a determination of efficient translation or exclude a pattern for inefficient translation. It does not teach what periodicity or phase corresponds to these. Applicant's arguments reinforce the examiner's position that the claims are an invitation to experiment.

Applicant incorrectly states that the claimed method is exemplified. As stated in the prior Office action, the example (beginning at page 19) discloses a method of calculating free energy between base pairs and successively repeating the process for other alignments. However, this is not all the claimed method requires. The example does not speak to the criteria by which translation can be determined to be efficient or inefficient.

Applicant has not responded to the queries set forth in the prior Office action with respect to the claimed method. Within the context of the claims, what information does strength of the periodic signal (claim 6) provide with respect to efficient translation? What is the quantitative indicator required by claims 7-10? How is it computed from the strength of the periodic signal? The specification does not exemplify nor provide guidance on the replacement of at least one base in the substrate nucleic acid sequence to result in sufficiency of translation efficiency. Which position(s) should be replaced? What bases are to be used for replacement? What defines a nucleic acid sequence having sufficiency of translation? How is this attribute determined? (See claims 8-10.) With respect to claim 11, the specification does not exemplify nor provide guidance on detecting a phase shift and making an evaluation as to whether the substrate nucleic acid sequence remains a candidate for efficient translation. Must some value be calculated? What defines a nucleic acid sequence having such a phase shift? How is this attribute determined?

Claims 1-2 and 4-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 does not make clear what type of “periodic cycle and phase” must be present to indicate that the substrate nucleic acid sequence is a candidate for efficient translation. The claim does not make clear what the metes and bounds of “correct phase” are. See also claims 21-22.

Claims 21 and 22, step (f) requires successively repeating steps (c) through (e) to determine a series of binding strengths. Step (g) is confusing in referring again to successively repeating steps (c) through (e). It appears that the binding strengths of the first, second, and third binding strengths and those of step (f) (i.e. each binding strength determined at every alignment) are used to generate the binding strength pattern. However, the language in step (g) implies that perhaps only the binding strengths determined in step (f) are used and that the first, second, and third binding strengths are omitted. In addition, the claims do not make clear what type of “periodic cycle and phase” must be present to indicate that the substrate nucleic acid sequence is a candidate for efficient translation. The claims do not make clear what the metes and bounds of “correct phase” are.

Claim 8 is further unclear as to whether the at least one base replacement is performed once (steps (c) through (j)) or successive times until the presence of sufficient translation efficiency is found. In view of dependent claim 10, the claim’s intent appears to be that it would occur once. It is unclear whether changes to the underlying encoded protein are permitted and/or what replacements can be made. It is unclear from the claim what level of translation efficiency is required to lead to the execution of step (k). Claim 9 is confusing for these same reasons.

Claim 10 does not make clear what level of efficiency of translation is required to meet the limitation of the claim and terminate the repeating steps.

Claim 14 remains confusing in its dependency upon claim 1. The added final step is “predicting likelihood for efficient translation.” This predicting uses “said already determined binding strengths.” This appears to be directed to a different method than claim 1 which is screening a nucleic acid sequence for efficient translation. That is, this final step does not result in the stated goal of claim 1. If applicant believes that this likelihood prediction is what is intended by the preamble recitation of screening for efficient translation, then claim 1 is either incomplete and/or claim 14 does not clearly further limit claim 1.

Claims 18-20 remain confusing in each reciting an additional step of calculating a value to determine if the sequence is a candidate for efficient translation. It is unclear if the value itself is the indicator of whether or not the sequence is efficiently translated and if so which values indicate efficient translation and which indicate inefficient translation or whether this value is used in some unspecified way to make this determination.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

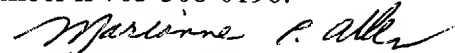
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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 703-308-0666. The examiner can normally be reached on Monday-Thursday, 5:30 am - 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703-308-4028. The fax phone number for the organization where this application or proceeding is assigned is 703-305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Marianne P. Allen
Primary Examiner
Art Unit 1631

mpa